DEC 9 2005

Tab 3 Non-Confidential Summary of Safety and Effectiveness

Substantial Equivalence

The modified device has the following similarities to the previously cleared predicate devices:

- Same intended use.
- Same operating principle.
- Same technology.
- Same manufacturing process.

Design verification tests were performed on the I-neb Insight AAD System as a result of the risk analysis and product requirements. All tests were verified to meet the required acceptance criteria. Profile Therapeutics plc has determined that the modifications have no impact on the safety and effectiveness of the device. In summary, the device described in this submission is substantially equivalent to the predicate devices.

The modified device complies with the applicable standards referenced in the Guidance for FDA Reviewers and Industry "Guidance for the Content of Pre-market Submissions for Software Contained in Medical Devices," May 1998.

Intended Use

The intended purpose of the I-neb AAD System is that is it is an ultrasonic (vibrating mesh) nebulizer system designed to aerosolize liquid medication approved for use with the I-neb AAD System for inhalation by the patient in the home care, nursing home, sub-acute institution, or hospital environment.

Device Description

The I-neb Insight AAD System is a portable, single patient use, reusable, ultrasonic (vibrating mesh) nebulizer system designed to aerosolize liquid medication approved for use with the I-neb AAD System for inhalation by the patient in the home care, nursing home, sub-acute institution, or hospital environment.

I-neb insight has a monitoring function and it provides feedback to both patient and clinician regarding different aspects of inhaled aerosol therapy.
The I-neb insight is designed to be used by the clinician to display a patients breathing performance so that it can be used to aid the teaching of optimized

breathing. It may also be used by the clinician to interrogate the I-Neb AAD System Patient Logging System (PLS) which can provide the clinician with device information that they need to make informed prescribing decisions for patients.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 9 2005

Profile Therapeutics PLC
C/O Ms. Barbara Campbell
Respironics, Incorporated
1010 Murry Ridge Lane
Murrysville, Pennsylvania 15668-8525

Re: K052941
Trade/Device Name: I-neb Insight AAD System
Regulation Number: 868.5630
Regulation Name: Nebulizer
Regulatory Class: II
Product Code: CAF
Dated: November 15, 2005
Received: November 18, 2005

Dear Ms. Campbell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

RESPIRONICS
www.respironics.com

Tab 1 Indications for use

Indications for Use

510(k) Number: K (To be assigned)

Device Name: I-neb Insight AAD System

Intended Use: The intended purpose of the I-neb Insight AAD System is that is it is an ultrasonic (vibrating mesh) nebulizer system designed to aerosolize liquid medication approved for use with the I-neb AAD System for inhalation by the patient in the home care, nursing home, sub-acute institution, or hospital environment.

Prescription Use X **or** **Over-the-counter use** ___

(Per CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

K052941